510(k) Summary – Hemoglobin Gen. 3

JAN 2 0 2011

K102914

Introduction

Roche Diagnostics Corporation hereby submits this Special 510(k) according to the requirements of 21 CFR 807.92. to provides sufficient detail to understand the basis for a determination of substantial equivalence for the Tina-quant HbA1c assay Gen 3.

Submitter. name. address. contact

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Contact person: Kathie Goodwin

Date prepared: 9/31/2010

Device name

Proprietary name: Tina-quant HbA1c Gen. 3

Common name: HbA1c Gen. 3

Classification name: Glycosylated Hemoglobin Assay

Product code: LCP

Device description

With the Tina-Quant Hemoglobin A1c Gen. 3 test system. the anticoagulated whole blood specimen is hemolyzed prior to determination of HbA1c by an turbidimetric inhibition immunoassay (TINIA). Liberated hemoglobin (Hb) in the hemolyzed sample is converted to a derivative having a characteristic absorption spectrum and measured bichromatically. The instrument calculates the % HbA1c from the HbA1c/ Hb ratio according to a user selected protocol.

Intended use

The Tina-Quant Hemoglobin A1c Gen. test is in vitro diagnostic reagent system intended for use on the COBAS INTEGRA 800 analyzers for the quantitative determination of mmol/mol hemoglobin A1c (IFCC) and % hemoglobin A1c ((DCCT/NGSP) in hemolysate or whole blood on Roche clinical chemistry analyzers. HbA1c determinations are useful for monitoring of long-term blood glucose control in individuals with diabetes mellitus.

Predicate device

We claim substantial equivalence to the Tina-quant HbA1c Gen 2 assay cleared in K072714.

Continued on next page

510(k) Summary – insert device name. Continued

Substantial equivalence – similarities and differences

The following table compares the HbA1c Gen 2 assay with the HbA1c Gen. 3 assay.

Feature	HbA1c Gen. 2 K072714	HbA1c Gen. 3
Intended Use	**Whole blood application** In vitro test for the quantitative determination of percent hemoglobin A1c [HbA1c (%)] in whole blood on Roche clinical chemistry analyzers . **Hemolysate Application**: In vitro test for the Quantitative determination of percent hemoglobin A1c [HbA1c (%)] in hemolysate prepared from whole blood on Roche clinical chemistry analyzers	**Whole blood application** In vitro test for the quantitative determination of mmol/mol hemoglobin A1c (IFCC) and % hemoglobin A1c (DCCT/NGSP) in whole blood on Roche clinical chemistry analyzers **Hemolysate Application** In vitro test for the quantitative determination of mmol/mol hemoglobin A1c (IFCC) and percent hemoglobin A1c (DCCT/NGSP) in hemolysate prepared from whole blood on Roche clinical chemistry analyzers.
Assay Protocol		

Feature	HbA1c Gen. 2 K072714	HbA1c Gen. 3
Sample Types	**Whole blood/Hemolysate applications:** Anticoagulated venous or capillary blood with the following anticoagulants: Li-heparin Na-heparin K2-EDTA K3-EDTA potassium fluoride/Na_2-EDTA Sodium fluoride/Na-EDTA Sodium fluoride/potassium oxalate	**Whole blood/Hemolysate applications:** Anticoagulated venous or capillary blood with the following anticoagulants: Li-heparin Na-heparin K2-EDTA K3-EDTA potassium fluoride/Na_2-EDTA Sodium fluoride/Na-EDTA Sodium fluoride/potassium oxalate
Labeled Instrument Platform	Integra 400/400 plus Integra 800	same
Calibrator	Cfas HbA1c	same
Calibration Frequency	Each lot. every 29 days. and as required following quality control procedures	same
Calibration mode	Logit/log 5	Spline
Controls	HbA1c Control N HbA1c Control P	same
Reagent Stability	2-8 °C until expiration date on-board in use @ 8°C 28 days	Same Integra 400/400plus: on board in use @ 10-15°C 28 days Integra 800 on-board in use @ 8°C: 28 days

<table>
<tr><th>Feature</th><th>HbA1c Gen. 2
K072714</th><th>HbA1c Gen. 3</th></tr>
<tr><td>Measuring Range</td><td>Integra 400/400 plus
Hb: 4 – 35 g/dL
HbA1c: 0.3 – 2.6 g/dL*

* Based on concentration of the highest standard

Integra 800
Hb: 4 – 35 g/dL
HbA1c: 0.3 – 3.4 g/dL*</td><td>Integra 400/400 plus
Hb: 4 – 40 g/dL
HbA1c:same

Integra 800
Hb: 4 – 40 g/dL
HbA1c: 0.3 – 2.6 g/dL</td></tr>
<tr><td>Precision</td><td>Whole blood application
Within-run:

0.8% @ 5.4 % HbA1c
0.9% @ 10.2 % HbA1c</td><td>Whole blood application
Repeatability:

<table><tr><th>sample</th><th>% CV</th><th>%HbA1c</th></tr><tr><td>HbA1c Control N</td><td>1.1</td><td>5.6</td></tr><tr><td>HbA1c Control P</td><td>0.8%</td><td>10.3</td></tr><tr><td>human sample 1</td><td>0.9%</td><td>4.7</td></tr><tr><td>human sample 2</td><td>0.8</td><td>5.8</td></tr><tr><td>human sample 3:</td><td>0.7</td><td>8.7</td></tr><tr><td>human sample 4</td><td>1.5</td><td>12.4</td></tr></table></td></tr>
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<tr><th>Feature</th><th>HbA1c Gen. 2
K072714</th><th>HbA1c Gen. 3</th></tr>
<tr><td>Precision, cont…</td><td>Whole blood application, cont…

Between day
1.3% @ 5.3 % HbA1c
1.0% @ 10.3 % HbA1c

Hemolysate Application:
Within-run:
1.0% @ 5.5 % HbA1c
0.6% @ 10.6 % HbA1c

Between day

1.0 % @ 5.3 % HbA1c
0.8% @ 10.7 % HbA1c</td><td>Whole blood application, cont…

Intermediate precision:
<table><tr><th>sample</th><th>% CV</th><th>%HbA1c</th></tr><tr><td>HbA1c Control N</td><td>1.3</td><td>5.6</td></tr><tr><td>HbA1c Control P</td><td>0.9</td><td>10.3</td></tr><tr><td>human sample 1</td><td>1.1</td><td>4.7</td></tr><tr><td>human sample 2</td><td>1.1</td><td>5.8</td></tr><tr><td>human sample 3:</td><td>0.8</td><td>8.7</td></tr><tr><td>human sample 4</td><td>1.6</td><td>12.4</td></tr></table>
Hemolysate Application
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Feature	HbA1c Gen. 2 K072714	HbA1c Gen. 3
Analytical Sensitivity	LDL Hb: 0.5 g/dL HbA1c: 0.1 g/dL	LoB Hb=0.50 g/dL HbA1c: 0.19 g/dL LoD Hb=1.0 g/dL HbA1c: 0.29 g/dL
Analytical Specificity	Hb: Labile HbA1c (pre-HbA1c). acetylated Hb. carbamylated Hb do not affect the assay result Hb variants: Specimens containing high amounts of HbF(> 10%) may yield lower than expected HbA1c results	same same
Endogenous Interferences	Icterus: no significant interference Lipemia: no significant interference up to a triglycerides conc of 600 mg/dL (Integra 400/400 plus) and 800 mg/dL (Integra 800) Rheumatoid factors: no significant interference up to 750 IU/mL Glycemia: no significant interference up to 1000 mg/dL	Same Lipemia: no significant interference up to a Intralipid conc of 800 mg/dL same same
Expected Values	2.9 – 4.2 % HbA1c (acc. to IFCC) 4.8 -5.9 % HbA1c (acc. to DCCT/NGSP)	29 – 42 mmol/L HbA1c (acc. IFCC) same

Feature	HbA1c Gen. 2 K072714	HbA1c Gen. 3
Determination of HbA1c	Turbidimetric immunoinhibition (TINIA). Antigen-antibody complexes are formed and excess Ab aggregate with polyhapten to form insoluble complexes	same
Determination of Hb	Bichromatic photometric determination after conversion to a colored derivate	same
Pretreatment	**Whole blood application** automated on-board sample pretreatment with hemolyzing reagent **Hemolysate Application**: Manual pretreatment with hemolyzing reagent	same same
Antibody	Polyclonal anti-HbA1c from sheep blood	same
Reporting units	% HbA1c NGSP / DCCT	mmol/mol IFCC % HbA1c NGSP/DCCT
Equation used for final HbA1c value	Protocol 1 (acc. to IFCC) HbA1c(%)=(HbA1c/Hb)x100 Protocol 2 (acc. to DCCT/NGSP) HbA1c(%)=(HbA1c/Hb)x87.6+2.27	Protocol 1 (acc. to IFCC) HbA1c(mmol/mol)=(HbA1c/Hb) x1000 Protocol 2(acc. toDCCT/NGSP) HbA1c(%)=(HbA1c/Hb)x91.5+2.15

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Roche Diagnostics Corporation
c/o Ms. Kathie Goodwin
9115 Hague Road
Indianapolis, Indiana 46250

JAN 20 2011

Re: k102914
Trade Name: Roche Tina Quant HbA1c Gen. 3 Assay
Regulation Number: 21 CFR §864.7470
Regulation Name: Glycosylated hemoglobin assay
Regulatory Class: Class II
Product Codes: LCP
Dated: December 20, 2010
Received: December 21, 2010

Dear Ms. Goodwin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K102914

Device Name: Tina-quant HbA1c Gen. 3

Indications for Use:

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Prescription Use ___x___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K102914